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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,325	08/15/2001	Ashley J. Birkett	ICC-103.1 US 83502	3946
24628	7590	10/20/2003	EXAMINER	
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	
			DATE MAILED: 10/20/2003	

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/931,325

Applicant(s)

BIRKETT, ASHLEY J.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-17, 19, 20, 22-30, 32-37, 39-43, 45, 46, 48, 49, 51, 53, 54, 56-58, 60-65 and 67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14, 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continuation of Disposition of Claims: Claims pending in the application are 1-11,13-17,19,20,22-30,32-37,39-43,45,46,48,49,51,53,54,56-58 and 60-67.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-11, 13-17, 19, 20, 22-30, 32-37, 39-43, 45, 46, 48, 49, 51, 53, 54, 56-58, and 60-67 are pending in the present application. These claims were either rejected, or objected to as in improper claim format, in the prior action, mailed on February 10, 2003. In the Response filed on July 15, 2003, the claims drawn to non-elected inventions were cancelled from the application, and claim 1, 9, 27, 35, 56, 60-65, and 66 were amended.

2. It is noted that claim 66 has been indicated as cancelled on page 3 of the Response, but as amended in the claim listing. For the purposes of this action, the claim is treated as amended but withdrawn as to a non-elected embodiment (the claim reads on a peptide comprising the T-cell epitope of SEQ ID NO: 25- not an elected embodiment). However, clarification of the Applicant's intentions regarding this claim is requested in the response to this action.

### ***Information Disclosure Statement***

3. The information disclosure statements (IDS) submitted on July 15, 2003, and February 24, 2003, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

### ***Specification***

4. **(Prior Objection-Withdrawn)** The disclosure was objected for several informalities. In view of the amendments made to the specification in the Response, the objection is withdrawn.

***Claim Objections***

5. **(Prior Objection-Withdrawn)** Claims 61-66 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from multiple claims in alternative form only. See MPEP § 608.01(n). In view of the Amendments to these claims, the objection is withdrawn. It is noted that, in view of the amendments to these claims, claim 66 has also been withdrawn from consideration.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **(Prior Rejection- Maintained)** Claims 9-11, 13-17, 19, 20, 22-26, 35-37, 39-43, 45, 46, 48, 49, 51, 53, 54, and 56-58 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims describe a recombinant HBc protein wherein Domain III of the protein “consists essentially of the HBc sequence from position 86 through position 135” and Domain IV of the protein is peptide bonded to the residue at position 135, and Domain II comprises residues 76 to 85 of HBc. This claim is indefinite because it is not clear what is meant by the requirement that Domain III “consists essentially of the HBc sequence from position 86 through position 135.” This indefiniteness arises, in part, from the requirements of the claim that Domain III is surrounded on one side by a sequence terminating with residue 85

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and on the other side by one that requires that it is bound to Domain III through a peptide bond with residue 135, and in part from the use of the language “consisting essentially of.” The Applicant traverses this rejection on the grounds that the identified language reads on changes within the identified sequence itself, rather than additions to the termini of the sequence. This traversal is not found persuasive.

As indicated in MPEP § 211.03, the language consisting essentially of “limits the scope of a claim to the specified materials... “and those that do not materially affect the basic and novel characteristics of the invention.” Thus, the MPEP clearly indicates that this language does not include changes to the specified material itself, but refers only to the scope of additional materials that may be added to it. In the present case, the Applicant has left no room for the addition of further materials to the specified material of Domain III, and the Applicant has nowhere provided any support for their newly suggested interpretation for the language “consisting essentially of.” In view of this, the Applicant’s traversal of the rejection is not found persuasive, and the rejection is maintained. Amended claims 61-65 have also been amended to include the rejected language, the rejection is therefore extended to these claims.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. **(Prior Rejection-Withdrawn)** Claims 1-5, 7, 8, 27-30, 32-34, 60, and 67 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being

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enabling for chimeric HBc molecules wherein HBc residues 1-4 have been replaced, does not reasonably provide enablement for HBc chimers where these residues are absent. In view of the amendments to the claims, this rejection is withdrawn.

10. **(Prior Rejection- Maintained)** Claims 9-11, 13-17, 19, 20, 22-26, 35-37, 39-43, 45, 46, 48, 49, 51, 53, 54, and 56-57 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant traverses this rejection on substantially the same grounds as was indicated with reference to the indefiniteness rejection above. For the same reasons as indicated above, the Applicant's traversal of the rejection is not found persuasive, and the rejection is maintained. Amended claims 61-65 have also been amended to include the rejected language, the rejection is therefore extended to these claims.

11. **(Prior Rejection-Withdrawn)** Claims 1-11, 13-16, 19, 22-24, 26-30, 32-37, 39-42, 45, 48, 49, 53, 54, 56-58, 60, and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for HBc chimeric proteins comprising insertions of the disclosed Plasmodium falciparum epitopes, does not reasonably provide enablement for an HBc chimeric protein wherein any Plasmodium epitope has been inserted in the protein. In view of the Applicant's arguments and Declaration, the rejection is withdrawn.

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12. **(Prior Rejection-Withdrawn)** Claims 1-11, 27-30, 32-34, 56-58, 60 and 67 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for HBc chimeres wherein Domain IV of the protein comprises the HBc sequence of residues 136-140, does not reasonably provide enablement for HBc chimeres that do not comprise these residues in Domain IV. In view of the amendments to the claims, the rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. **(Prior Rejection- Maintained in Part)** Claims 1-4, 6, 7-11, 13-17, 19, 20, 22-30, 32-37, 39-43, 45, 46, 48, 49, 51, 53, 54, 56-58, 60 and 67 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Pumpens (Intervirology 38:63-74) in view of Nardin PCT (WO 98/31382), Nardin (Science 246:1603-1606), Schödel ( J. Exp. Med. 180:1037-1046), Bernardi (DE 3741183), Kratz (PNAS 96: 1915-1920), and Metzger ( J. Gen. Virol., 79 :587-590). The rejected claims read on recombinant HBc chimeric proteins comprising a Plasmodium falciparum B-cell epitope (B epitope) between HBc residues 78 and 79, and optionally including a T-cell Plasmodium falciparum epitope (T epitope) at the C-terminus of the protein. The rejection is also extended to amended claims 61, 64, and 65.



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The Applicant begins the traversal with the statement that “any rejection that requires the amalgamation of six teachings is suspect...” and concludes that from this rule, the present rejection is suspect. The Examiner would like to bring Applicant’s attention to MPEP § 2145, part V, stating precisely the opposite of the Applicant’s supposed rule. The number of references alone does not weigh against the finding of obviousness. Thus, this argument is not found persuasive.

The Applicant also argues in traversal that the antigenic results achieved with the presently claimed invention were far superior to those of the prior art in the Balb/c mice models. The Examiner agrees with this statement insofar as the art is discussing the (NANP)<sub>4</sub> Plasmodium antigen repeat. However, the Applicant’s argument does not extend to the use of other Plasmodium antigens. For example, as can be seen in Table 4 of the Schödel reference, similar results to those achieved by the Applicant with the (NANP)<sub>4</sub> antigenic repeat were achieved in the reference using the (DP<sub>2</sub>NPN)<sub>2</sub> epitope. Thus, the improved results argued by the Applicant, although distinguishing the claimed antigen from the prior art to the extent that it reads on the use of the (NANP)<sub>4</sub> antigen, does not necessarily distinguish from the art with regards to any Plasmodium antigen. The Applicant has not demonstrated that the insertion of any Plasmodium antigen between residues 78 and 79 would result in an increase in that antigen’s efficacy. It is noted however that the art does recognize the amino acid 78-79 site as a preferred insertion site for foreign epitopes. See, Wynne et al., Mol Cell 3: 771-80 (of record in the IDS of February 2003). Thus, while the art does not render obvious the particular placement of the (NANP)<sub>4</sub> Plasmodium falciparum epitope in view of the improved performance of this epitope in that site when injected into Balb/c mice, the art does render obvious the claimed chimeric protein

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wherein the epitope may be any Plasmodium epitope. This is because the performances of the different epitopes have been shown to vary (Schödel), and as the Applicant has not demonstrated that the antigenicity of all epitopes would dramatically improve by placement between residues 78 and 79. The rejection is therefore withdrawn as to claims 13-15, and 39-41, but maintained with regards to the remaining claims for the reasons above, and for the reasons of record.

15. **(New Rejection- Based on Reference submitted in IDS)** Claims 1-11, 16, 17, 19, 20, 22-30, 32-37, 42, 43, 45, 46, 48, 49, 51, 53, 54, 56-58, 60 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pumpens in view of Nardin PCT (WO 98/31382), Nardin (Science 246:1603-1606), Schödel, Bernardi, Kratz, and Metzger as applied to claim 1 above, and further in view of Colman et al., U.S. Patent 5,614,194 (of record in the IDS submitted on February 24, 2003). This rejection is focused on the limitations of claim 5. Claim 5 further limits the teachings of claim 1 to embodiments wherein the Plasmodium is *P. vivax*. The references other than Colman have been described above, and in the prior action. Colman teaches the use of antigenic repeats from Plasmodium CS proteins, including *P. vivax*, as an anti-Plasmodium antigen. See e.g., claim 4. It would therefore have been obvious to use such an epitope in the chimeric protein suggested by the other references.

### ***Conclusion***

16. No claims are allowed.

17. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on February 24, 2003 prompted the new ground(s) of

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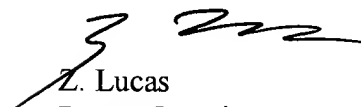
rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
October 15, 2003

  
JAMES HOUSEL 10/18/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600